

AUG 25 1995



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
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Washington, D.C. 20231

#44

Dominic M. Mezzapelle  
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Bristol-Myers Squibb Company  
345 Park Avenue  
New York, NY 10154

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,978,655

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,978,655, which claims the human drug product ZERIT, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 189 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 16, 1994. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (1,805 - 698) + 179 \\ &= 733 \text{ days}\end{aligned}$$

Since the regulatory review period began January 19, 1989, before the patent issued (December 18, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 19, 1989 to December 18, 1990 is 698 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $1,805 - 698 = 1,107$  days. ) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 24, 1994) when added to the period of extension calculated above (733 days) cannot exceed fourteen years. The period of extension is thus limited to June 24, 2008, by operation of 35 U.S.C. § 156(c)(3). Since the original patent term of seventeen years (35 U.S.C. § 154) would expire on December 18, 2007, the period of extension is the number of days to extend the term of the patent from its expiration date to and including June 24, 2008, or 189 days.

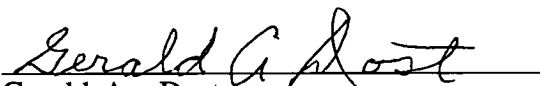
The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension

of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 189 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,978,655
Granted:	December 18, 1990
Applicant:	Tai-Shun Lin et al.
Owner of Record:	Yale University
Title:	USE OF 3'-DEOXYTHYMIDIN-2'-ENE (3'DEOXY-2',3'-DIDEHYDROTHYMIDINE) IN TREATING PATIENTS INFECTED WITH RETROVIRUSES
Classification:	514/50
Product Trade Name:	ZERIT
Term Extended:	189 days

  
Gerald A. Dost  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

RE: ZERIT  
FDA Docket No.: 94E-0332